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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,086	03/03/2004	Challen W. Waychoff II	29917/04000	4895
27874	7590	11/02/2005		
CALFEE, HALTER & GRISWOLD, LLP 1110 FIFTH THIRD CENTER 21 EAST STATE STREET COLUMBUS, OH 43215-4243			EXAMINER MCCORKLE, MELISSA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/792,086	<b>Applicant(s)</b> WAYCHOFF, CHALLEN W.	
	<b>Examiner</b> Melissa A. McCorkle	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/3/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Colon Hydrotherapy Device in the reply filed on 9/26/05 is acknowledged. The traversal is on the ground(s) that there is not a serious burden on the examiner. This is not found persuasive because the distinct inventions are shown to have different statuses in the art, therefore requiring different class searches, which is burdensome on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (6,761,702) in view of Shu (6,918,517). Smith discloses applicant's basic inventive concept of a colonic hydrotherapy device substantially as claimed with the

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exception of a nozzle further comprising a plurality of water outlets. Shu shows the feature to be old in the hydrotherapy devices art. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Shu to modify the hydrotherapy device of Smith by replacing the nozzle with the nozzle further comprising a plurality of water outlets (see Shu abstract) for the purpose of cleansing the perianal region.

Smith discloses a colon hydrotherapy device comprising a housing (10), wherein said housing is adapted to receive fluid inflow (26), and wherein said housing further comprises a first internal chamber (A) extending substantially through the length of said housing (fig 2) and stem for fluid inflow and a second internal chamber (B) distinct from said first chamber (fig 2) for fluid outflow extending from posterior to anterior portion of housing (fig 2), an anterior portion (16), a tapered posterior portion connected to anterior portion (32), a stem on exterior of housing (28), and a nozzle (claim 5) attached to said housing (fig 2 part 38) comprising a primary water inlet (26), a source of pressurized water (col 4 lines 1-5), a water input line attached to said stem (fig 2) and a drainage line attached to said housing (32).

5. Claims 2, 4 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith in view of Shu as applied to claims 1, 3 and 5-7 above, and further in view of Ouelette (4,842,580). Smith and Shu disclose applicant's basic inventive concept of a colonic hydrotherapy device substantially as claimed with the exception of an insertion rod residing in said housing. Ouelette shows this feature to be old in the hydrotherapy devices art. It would have been obvious to one of ordinary skill in the art at the time of

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applicant's invention from the teaching of Oulette to modify the device of Smith and Shu by adding an insertion rod (28) that resides in said housing (fig 1) to facilitate insertion of the speculum (col 2 line 58).

6. Hawks discloses the insertion rod further comprising a rounded tip at one end (36 and col 3 lines 57-60), a groove in said rounded tip corresponding to said primary water inlet (14), a planar grasping member at the end of said insertion rod opposite said tip (34), further comprising at least one notch for stabilizing said insertion rod with device (32).

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hawks (4,943,285) discloses an undulating rectal speculum; Mendieta et al (DE4427067A1) discloses a cannula for enemas and hydrotherapy of the colon; Wood (1,658,754) discloses a medical irrigation apparatus; Bried (2,691,373) discloses a colon flushing nozzle with dissolvable tip; Glassman (5,899,878) discloses a nasal irrigation system; Hawks (5,351,674) discloses an inlet tube for a speculum; Shilling et al (5,176,630) discloses a rectal insertion device and control valve means therefor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa A. McCorkle whose telephone number is (571) 272-2773. The examiner can normally be reached on Monday - Friday, 9am - 5:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melissa A McCorkle  
Examiner  
Art Unit 3763

MAM  
10/27/05



**NICHOLAS D. LUCCHESI**  
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